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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/101,413 08/07/98 STAUSS

H RFMS102

EXAMINER
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HM22/0628

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ART UNIT	PAPER NUMBER

1644

*22*

DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/101,413

Applicant(s)

Stauss, H.

Examiner  
G. R. Ewoldt

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4/2/01 and 6/12/01
- 2a) ☐ This action is FINAL.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 25-29 is/are pending in the application.
- 4a) Of the above, claim(s) 9-13 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14-18, 25, 26, 28, and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The request filed on 6/12/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/101,413 is acceptable and a CPA has been established. An action on the CPA follows.

2. A restriction was required under 35 U.S.C. § 121 in the parent application, as set forth in Paper No. 8, mailed 8/26/99.

Applicant elected Group II, claims 1-18, and the species, hematologic malignancies and GATA-1 and WT-1, with traverse. This restriction requirement is hereby reiterated.

The requirement is still deemed proper for the reasons of record as set forth in Paper No. 10, mailed 1/19/00, and is therefore made FINAL.

3. Claims 9-13 and 27 are withdrawn from further consideration by the examiner as being drawn to non-elected species of the elected invention.

Claims 1-8, 14-18, and newly amended Claims 25-26, and 28-29 read on the elected species and are being acted upon.

4. In view of Applicant's amendment and response, filed 4/02/01, all previous rejections have been withdrawn. Applicant is advised, however, that should the claims be amended to recite the previously rejected method of treating a patient, the rejections previously made to said claims under 35 U.S.C. § 102 and § 103 would be reintroduced in regard to the pending claims as new rejections comprising new issues. Given the withdrawal of the previous rejections, Applicant's arguments, filed 4/02/01, have been rendered moot.

5. The following are New Grounds of Rejection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8, 14-18, 25-26, and 28-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claim 1 it is unclear what the term "abnormal molecule" means, as the term has not been defined in the specification,

B) In claim 5 it is unclear what the term "mutant polypeptide" means, as the term has not been defined in the specification,

C) In claim 6, the term "wherein the polypeptide is present at a higher level in the diseased cells" is vague and indefinite as the term "higher level" has not been defined in the specification. Note that the similar term, a polypeptide present in "an abnormally elevated amount" is not indefinite as said term has been defined as >1.2 times the concentration found in a normal cell.

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-8, 14-18, 25-26, and 28-29 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) "A method of killing cells in a patient" (Claim 1),
- B) "and the CTLs kill the presenting cells" (Claim 1),
- C) wherein "the cells to be killed" (Claims 1 and 26),

Applicant's amendment, filed 4/02/01, asserts that no new matter has been added, however, no specific passages in the specification are offered in support of the new limitations.

10. Claims 1-8, 14-18, 25-26, and 28-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of an "abnormal molecule" or a "mutant polypeptide". The specification fails to define either term. Additionally, the specification fails to disclose any examples of either abnormal molecules or a mutant polypeptides. As both terms encompass essentially unlimited genuses, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
June 26, 2001

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